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EXAMINER
CHAN, RICHARD

ART UNIT	PAPER NUMBER
2618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,492	EDER ET AL.	
	Examiner	Art Unit	
	RICHARD CHAN	2618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20 and 22-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20, 22-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 2/03/09 have been fully considered but they are not persuasive.

With respect to applicant's arguments regarding claim 20, the applicant submits the examiner misinterprets the teachings of Nygard. The examiner points to the applicant's remarks, specifically page 10 second paragraph (last 4 lines) wherein the applicant states "In Fact, Nygard describes determining the potential differences at two electrodes as being a single measurement." (Col.4 line 4-6, Nygard also mentions wherein a fully differential input stage could be used instead of a single ended amplifier which would take the difference of the measured values)

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 20, 22-25, 27, 29-34, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy (US 5,999,856) in view of Nygard et al (US 5,758,651 B2).

Regarding claim 20, Kennedy discloses an evoked neural response measuring device comprising:

a first implantable subsystem 215 comprising a high gain amplifier having a signal input, and an electrode array configured to provide stimulation to the auditory nerve 50 (Col.6 line 58-61), and further configured to successively detect discrete values corresponding with electronics unit 225 an evoked neural response from the auditory nerve to said stimulation;

and a second subsystem configured to reconstruct said plurality of discrete values into a continuous waveform,

(Col.7 Line 38-44) and (Col.6 line 43-61)

and a second subsystem configured to reconstruct said plurality of discrete values into a continuous waveform. (Col.7 line 1-56)

However the Kennedy reference does not specifically disclose wherein said high gain amplifier having a reference voltage input and a signal input, and an electrode array configured to provide stimulation to the auditory nerve wherein said first implantable subsystem is configured to set said reference voltage to a first of said discrete values at a first time and to a second of said detected discrete values at a second time, wherein said amplifier is configured to amplify the difference between the first and second discrete values thereby obtaining a plurality of discrete values collectively representing an unsaturated, high gain amplified version of the evoked neural response of the auditory nerve.

The Nygard reference however discloses wherein telemetry system with an electrode array 10 is used both for delivering electrical stimuli and for sensing evoked potentials. A stimulus pair 12 and 13 senses the difference is amplified by an amplifier 20. The difference being amplified is than sampled at intervals 16 and transmitted via a RF link. (Col.2 line 59 – Col.3 line 4, this pulse is decoded by a decoder which sends suitable compares to the EAP amplifier telemetry controller 35. Based on the value controls the stimulation of the selected pairs)

It would have been obvious to one of ordinary skill in the art to implement the amplification of the difference between the sensed pair as disclosed by Nygard to the auditory device in Kennedy in order to output the values to representing the neural response of the Kennedy reference. The examiner implements the teaching of Nygard as a system that takes values of measured response and converts the analog response to a digital response by comparing the measured value to that of a threshold (it is understood that a threshold is calculated based on calculating a difference between the first measured value and the next in order to commands to the telemetry controller of Nygard.)in order to relay an EAP measurement.

Regarding claim 22, Kennedy and Nygard combined disclose the device of claim 20, wherein said second subsystem comprises: an integrator 330 configured to reconstruct said plurality of detected discrete values into a continuous waveform. (Averaging) (Col.7 line 45-48)

Regarding claim 23, Kennedy and Nygard combined disclose the device of claim 21, wherein said first subsystem is configured to set reference voltage (Calibration output signal provided by electronics unit 225) input to said first of said detected discrete values of said evoked response at the commencement of each said time interval, and wherein said first subsystem is configured to set signal input (signal being delivered by output stimulator 215) to said second of said detected discrete values of said evoked response at end of each said interval. (Col.10 line 47-67)

Regarding claim 24, Kennedy and Nygard combined disclose the device of claim 21, wherein said first subsystem further comprises: a sample-and-hold circuit step 800 having an input from said electrode array configured to set the reference voltage of said amplifier equal to a present value of the evoked response at the commencement of each said interval. (Col.10 line 47-67)

Regarding claim 25, Kennedy discloses the method of measurement of an evoked neural response in a cochlear implant comprising:

stimulating a desired section of an auditory nerve to elicit an evoked neural response 50, (Col.6 line 43-61) via a first implanted subsystem (Col.6 line 58-61);

successively detecting the evoked neural response of the auditory nerve at a plurality of intervals via the first implanted subsystem to obtain a plurality of discrete values collectively representing an unsaturated, high gain amplified version of the

evoked neural response; and reconstructing said plurality of discrete values into a continuous waveform. (Col.7 line 1-56)

However the Kennedy reference does not specifically disclose wherein said high gain amplifier having a reference voltage input and a signal input, and an electrode array configured to provide stimulation to the auditory nerve wherein said first implantable subsystem is configured to set said reference voltage to a first of said discrete values at a first time and to a second of said detected discrete values at a second time, wherein said amplifier is configured to amplify the difference between the first and second discrete values thereby obtaining a plurality of discrete values collectively representing an unsaturated, high gain amplified version of the evoked neural response of the auditory nerve.

The Nygard reference however discloses wherein telemetry system with an electrode array 10 is used both for delivering electrical stimuli and for sensing evoked potentials. A stimulus pair 12 and 13 senses the difference is amplified by an amplifier 20. (Col.2 line 59 – Col.3 line 4)

It would have been obvious to one of ordinary skill in the art to implement the amplification of the difference between the sensed pair as disclosed by Nygard in order to calculate values to representing the neural response of the Kennedy reference.

Regarding claim 27, Kennedy and Nygard combined disclose the method of claim 25, wherein each altering of said reference voltage comprises: setting said

reference voltage equal to a present value of the evoked neural response at the commencement of each interval. (Col.10 line 47-67)

Regarding claim 29, Kennedy and Nygard combined disclose the method of claim 25, wherein setting the reference voltage of the high gain amplifier equal to said first value comprises: setting the reference voltage of the high gain amplifier equal to the present value of the evoked neural response at the commencement of each said interval. (Col.10 line 47-67)

Regarding claim 30, Kennedy and Nygard combined disclose the method of claim 25, wherein reconstructing said plurality of discrete values into the continuous waveform comprises: integrating said plurality of discrete values to obtain said continuous waveform. (Averaging) (Col.7 line 45-48)

Regarding claim 31, Kennedy and Nygard combined disclose the method of claim 25, wherein obtaining said first and second values comprises: utilizing one or more electrodes of an electrode array of a cochlear implant to obtain said values. (Col.7 line 1-56)

Regarding claim 32, Kennedy discloses the device for measuring of an evoked neural response in a cochlear implant comprising:

Means for simulating a desired of an auditory nerve to elicit an evoked neural response and for sampling the evoked neural response 50 (Col.6 line 58-61), (Col.6 line 43-61) a plurality of intervals to obtain a plurality of discrete values collectively representing an unsaturated, high gain amplified version of the evoked neural response; (Col.7 line 1-56) and means for reconstructing said plurality of discrete values into a continuous waveform. (Averaging) (Col.7 line 45-48)

The Nygard reference however discloses wherein telemetry system with an electrode array 10 is used both for delivering electrical stimuli and for sensing evoked potentials. A stimulus pair 12 and 13 senses the difference is amplified by an amplifier 20. (Col.2 line 59 – Col.3 line 4)

It would have been obvious to one of ordinary skill in the art to implement the amplification of the difference between the sensed pair as disclosed by Nygard in order to calculate values to representing the neural response of the Kennedy reference.

Regarding claim 33, Kennedy and Nygard combined disclose the device of claim 32, wherein said means for sampling the evoked neural response at the plurality of intervals includes: means for successively altering a reference voltage of a high gain amplifier at the commencement of each said interval such that each discrete value equals an amplified form of the voltage change in the evoked neural response over said interval. (Col.10 line 47-67)

Regarding claim 34, Kennedy and Nygard combined disclose the device of claim 33, wherein each means for altering said reference voltage comprises: means for setting said reference voltage equal to a present value of the evoked neural response. (Col.10 line 47-67)

Regarding claim 36, Kennedy and Nygard combined disclose the device of claim 35, wherein said means for setting the reference voltage of the high gain amplifier equal to said first value comprises: means for setting the reference voltage of the high gain amplifier equal to the present value of the evoked neural response at the commencement of each sample interval. (Col.10 line 47-67)

Regarding claim 37, Kennedy and Nygard combined disclose the device of claim 32 wherein said means for reconstructing said plurality of discrete values into a continuous waveform comprises: means for integrating said plurality of discrete values to obtain said continuous waveform representing an amplified form of said evoked neural response. (Averaging) (Col.7 line 45-48)

Regarding claim 38, Kennedy and Nygard combined disclose the device of claim 35, wherein said means for obtaining said first and second values comprises: means for utilizing one or more electrodes of an electrode array of a cochlear implant to obtain said values. (Col.7 line 1-56)

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Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RICHARD CHAN whose telephone number is (571)272-0570. The examiner can normally be reached on Mon - Fri (9AM - 5PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nay Maung can be reached on (571)272-7882. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nay A. Maung/
Supervisory Patent Examiner, Art Unit 2618

/Richard Chan/
Examiner, Art Unit 2618